

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION

UNITED STATES OF AMERICA

v.

ROBERT LANCE SCHUFFERT

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M-22-0145

CRIMINAL INFORMATION

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

Introduction

1. Science Production Products LLC ("SPP"), located in or around Harris County, Texas, imported, created, marketed, and distributed for sale purported bodybuilding and dietary supplements, including, but not limited to, Selective Androgen Receptor Modulators ("SARMs") in interstate and intrastate commerce.

2. According to SPP's corporate filings with the Texas Secretary of State, ROBERT LANCE SCHUFFERT was the owner and operator of SPP.

3. The true owner of SPP was "Owner-1," an individual residing in or around Harris, County Texas.

4. ROBERT LANCE SCHUFFERT worked for Owner-1 and was paid by Owner-1.

5. At the direction of Owner-1, SPP sold SARMs to various workout supplement retailers, including a workout supplement retailer located and operating within the McAllen Division of the Southern District of Texas and elsewhere ("Business-1").

6. The United States Food and Drug Administration (“FDA”) was the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* FDA’s primary purpose in enforcing the FDCA was to protect the health and safety of consumers in the United States. FDA’s responsibilities included regulating the manufacturing, labeling, and distribution of food and drugs shipped or received in interstate commerce. The requirements of the FDCA, in part, are meant to ensure that food and drugs sold for human use are safe and bear labeling that contains accurate and adequate information.

7. The FDCA defined a “drug” in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either. 21 U.S.C. § 321(g). Whether an article was a drug was determined by its intended use, which was defined at the time of the offense as “the objective intent of persons legally responsible for the labeling of drugs.” The intent was determined by “such person’s expressions or may be shown by the circumstances surrounding the distribution of the article.” Such intent could be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. 21 C.F.R. § 201.128.

8. A drug was misbranded under the FDCA if, among other things, its label was false or misleading in any particular. 21 U.S.C. § 352(a)(1).

9. It was a prohibited act for any person to cause drugs to become misbranded within the meaning of 21 U.S.C. § 352(a)(1), while they were held for sale after shipment of one or more of their components in interstate commerce. 21 U.S.C. § 331(k). Such a prohibited act was a felony violation when it was done with the intent to defraud and mislead. 21 U.S.C. § 333(a)(2).

10. SARMs were synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. FDA issued a public safety alert in 2017 warning consumers against ingesting body-building products containing SARMs because these products were linked to life-threatening reactions, including liver toxicity and increased risk of heart attack and stroke. One such SARM was a drug called Ostarine.

11. At the direction of Owner-1, SPP imported, manufactured, marketed, and sold a SARM product called Ostarine MK-2866.

12. At the direction of Owner-1, ROBERT LANCE SCHUFFERT sold SPP's SARM product Ostarine MK-2866 to various workout supplement retailers, including Business-1.

13. Ostarine MK-2866 was a drug because it was intended to affect the structure or function of the body in that: (a) its labeling contained the following dosage instructions: "[t]ake ½ dropper .5 ml twice daily with meals. Do not exceed 1 full dropper per day. You may cycle this product for 4-6 weeks before taking 4 weeks off;" (b) it was marketed as "pharmaceutical grade" and with "results guaranteed;" and (c) Business-1, a retailer to which SPP sold Ostarine MK-2866, marketed the product to increase lean muscle mass and lose unwanted fat.

14. SPP's SARM product Ostarine MK-2866 was a misbranded drug because its labeling was false or misleading in any particular, in that it was labeled as a "Research Product" but was in fact intended to be used by humans to increase lean muscle mass and lose unwanted fat.

15. At the direction of Owner-1, ROBERT LANCE SCHUFFERT and others, known and unknown, operated the business of SPP and worked with other companies to, among other things: (a) import SARMs from China through interstate commerce; (b) use the imported SARMs as components of a drug that ROBERT LANCE SCHUFFERT and others, known and unknown,

caused to become misbranded; and (c) distribute for sale such misbranded drug within the Southern District of Texas and elsewhere.

16. ROBERT LANCE SCHUFFERT knowingly took steps to mislead and defraud the Government and consumers in the sale of SARMS, including Ostarine MK-2866.

17. ROBERT LANCE SCHUFFERT knew the SARM ingredient in Ostarine MK-2866 was subject to scrutiny by Government law enforcement agencies, including the FDA, and to avoid this regulatory scrutiny, marketed and labeled the product as “for lab rat use only” and “for research purposes only” while simultaneously knowingly holding the product for sale to brick-and-mortar retailers, and thus intended to affect the structure or function of the body.

COUNT 1
(21 U.S.C. §§ 331(k) and 333(a)(2))

18. Paragraphs 1 through 17 are incorporated herein by reference.

19. On or about the approximate date listed below, in the Southern District of Texas and elsewhere, ROBERT LANCE SCHUFFERT with the intent to defraud and mislead, did, while the drug was held for sale and after its component had been shipped in interstate commerce, cause the product with the active ingredient listed below to be false or misleading in any particular, which act resulted in the drug being misbranded within the meaning of Title 21, United States Code, Section 352(a).

Approximate Date	SPP Product Name	Active Ingredient on Label	Other Labeling
May 18, 2020	JINTRO PHARMACEUTICALS MK-2866 Ostarine MK-2866	Ostarine MK-2866	“Research Product” “Suggested Use: Take ½ dropper .5 ml twice daily with meals. Do not exceed 1 full dropper per day. You may cycle this product for 4-6 weeks before taking 4 weeks off”

All in violation of 21 U.S.C. §§ 331(k) and 333(a)(2).

NOTICE OF CRIMINAL FORFEITURE
(18 U.S.C. §§ 981, 982; 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c))

The allegations contained in Count One of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(7) and Title 21, United States Code, Section 334 as authorized by Title 28, United States Code, Section 2461(c).

Pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(7) and Title 21, United States Code, Section 334 as authorized by Title 28, United States Code, Section 2461(c), upon Defendant's conviction of Count One of this Information, in violation of 21 U.S.C. 331(k), the Defendant shall forfeit to the United States of America any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds traceable to the offense.

MONEY JUDGMENT – SUBSTITUTE ASSETS


The United States gives notice that, in the event of conviction, the United States intends to seek a money judgment. Further, in the event that one or more conditions listed in Title 21, United States Code, Section 853(p) exist, the United States also gives notice that it will seek to forfeit any other property of the Defendant up to the amount of the money judgment. If any of the property described above, as a result of any act or omission of the Defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

JENNIFER B. LOWERY
UNITED STATES ATTORNEY


ASHA M. NATARAJAN
ASSISTANT UNITED STATES ATTORNEY


ANDREW R. SWARTZ
ASSISTANT UNITED STATES ATTORNEY